Notice of Allowability	Application No.	Applicant(s)	
	09/857,333	PHILLIPS ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *1,11,13,16,18,20,24,25 and 28-42*.

3. ☒ The drawings filed on *04 June 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *Attached* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Jon Eric Angell

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John MacDonald and Sima Kulkarni on 3/29/04, and Sima Kulkarni 4/1/04.

The application has been amended as follows:

1. (Currently amended) A method for ~~treating~~ reducing an inflammation in an animal ~~having inflammation caused by one or more of immune-mediated inflammation, osteoarthritis, rheumatoid arthritis, glomerulonephritis, colitis, or cystitis~~, comprising administering to the animal an effective amount of a composition comprising:

(a) a mycobacterial deoxyribonucleic acid obtained from a disrupted mycobacterium, wherein the mycobacterial deoxyribonucleic acid is preserved and complexed on a mycobacterial cell wall (BCC); and

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to ~~treat~~ reduce the inflammation.

2. (Cancel)

3-10. (Previously cancelled)

11. (Original) The method of Claim 1, wherein the effective amount is effective to induce the synthesis of cytokine IL-10.

12. (Cancel)

13. (Original) The method of Claim 1, wherein the pharmaceutically acceptable carrier is selected from the group consisting of a liquid carrier and a solid carrier.

14. (Cancel)

15. (Previously Cancelled)

16. (Currently amended) A method for ~~treating~~ reducing an inflammation in an animal ~~having inflammation~~, comprising administering to the animal an effective amount of a composition comprising *Mycobacterium phlei*-DNA preserved and complexed on a *Mycobacterium phlei* cell wall (MCC) and a pharmaceutically acceptable carrier, wherein the amount is effective to ~~treat~~ reduce the inflammation.

17. (Cancel)

18. (Currently amended) The method of Claim 16, wherein the effective amount is effective to induce the ~~synthesis~~ production of cytokine IL-10.

19. (Cancel)

20. (Original) The method of Claim 16, wherein the pharmaceutically acceptable carrier is selected from the group consisting of a liquid carrier and a solid carrier.

21-23. (Cancel)

24. (Previously Presented) The method of Claim 1, wherein the mycobacterial deoxyribonucleic acid and the mycobacterial cell wall are obtained from *Mycobacterium phlei.*

25. (Previously Presented) The method of Claim 2, wherein the mycobacterial deoxyribonucleic acid and the mycobacterial cell wall are obtained from *Mycobacterium phlei.*

26. (Cancel)

27. (Cancel)

28. (New) The method of Claim 1, wherein the animal has immune-mediated inflammation, osteoarthritis, rheumatoid arthritis, glomerulonephritis, colitis or cystitis.

29. (New) The method of Claim 1, wherein the animal has osteoarthritis.

30. (New) The method of Claim 1, wherein the animal has colitis.

31. (New) The method of Claim 1, wherein the mycobacterium is selected from the group consisting of *M. vaccae*, *M. chelonei*, *M. smegmatis*, *M. terrae*, *M. duvalii*, *M. tuberculosis*, *M. bovis* BCG, *M. avium*, *M. Szulgai*, *M. scrofulaceum*, *M. xenopi*, *M. kansaii*, *M. gastr*, *M. fortuitious*, and *M. asiaticum*.

32. (New) The method of Claim 16, wherein the animal has immune-mediated inflammation, osteoarthritis, rheumatoid arthritis, glomerulonephritis, colitis, or cystitis.

33. (New) The method of Claim 16, wherein the animal has osteoarthritis.

34. (New) The method of Claim 16, wherein the animal has colitis.

35. (New) A method for inducing IL-10 production in an animal comprising administering to the animal an effective amount of a composition comprising:

(a) a mycobacterial deoxyribonucleic acid obtained from a disrupted mycobacterium, the mycobacterial deoxyribonucleic acid preserved and complexed on a mycobacterial cell wall (BCC); and

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to induce IL-10 production.

36. (New) The method of Claim 35, wherein the pharmaceutically acceptable carrier is selected from the group consisting of a liquid carrier and a solid carrier.

37. (New) The method of Claim 35, wherein the mycobacterial deoxyribonucleic acid and the mycobacterial cell wall are obtained from *Mycobacterium phlei.*

38. (New) The method of Claim 35, wherein the mycobacterium is selected from the group consisting of *M. vaccae*, *M. chelonei*, *M. smegmatis*, *M. terrae*, *M. duvalii*, *M. tuberculosis*, *M. bovis* BCG, *M. avium*, *M. Szulgai*, *M. scrofulaceum*, *M. xenopi*, *M. kansaii*, *M. gastr*, *M. fortuitious*, and *M. asiaticum*.

39. (New) A method for inducing IL-10 production in an animal, comprising administering to the animal an effective amount of a composition comprising *Mycobacterium phlei*-DNA preserved and complexed on a *Mycobacterium phlei* cell wall

(MCC) and a pharmaceutically acceptable carrier, wherein the amount is effective to induce IL-10 production.

40. (New) The method of Claim 39, wherein the pharmaceutically acceptable carrier is selected from the group consisting of a liquid carrier and a solid carrier.

41. (New) The method of Claim 39, wherein the animal has immune-mediated inflammation, osteoarthritis, rheumatoid arthritis, glomerulonephritis, colitis, and cystitis.

42. (New) The method of Claim 22, wherein the mycobacterium is selected from the group consisting of *M. vaccae*, *M. chelonei*, *M. smegmatis*, *M. terrae*, *M. duvalii*, *M. tuberculosis*, *M. bovis* BCG, *M. avium*, *M. Szulgai*, *M. scrofulaceum*, *M. xenopi*, *M. kansaii*, *M. gastr*, *M. fortuitious*, and *M. asiaticum*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art Unit 1635

DAVE T. NGUYEN
PRIMARY EXAMINER